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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,141	07/18/2003	Takayuki Ohishi	09496/000M860-US0	5199
7278	7590	04/20/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			VALENTIN, JUAN D	
			ART UNIT	PAPER NUMBER
			2877	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/623,141

Applicant(s)

OHISHI ET AL.

Examiner

Juan D. Valentin II

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*pm*

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/25/06, 3/15/06</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Response to Arguments***

1. Applicant's arguments filed 01/25/2006 have been fully considered but they are not persuasive. With regards to claims Applicant has argued on page 8, lines 14-15 in the Remarks section of the amendment filed 1/25/2006 that "Sites does not disclose directing treatment in response to an ideal patient-specific blood parameter curve obtained previously" and further on page 9, lines 7-8, "Sites does not collect patient reference data through a previous treatment that can be used by a controlling or directing means". Applicant has not claimed specifically how the ideal blood treatment curve is obtained, but has claimed only that one exists, it is clear that Sites discloses an ideal blood parameter curve (Fig. 5b, col. 2, lines 62-64), applicants argument that Sites does not disclose obtaining this curve through a previous blood treatment is noted, however such claim language is not found in either independent claim 1 or 11. Further, with regards to claims 2, 6, 12, 16, & 21, applicant has argued that Sites in view of Osten does not disclose an approximation function/equation calculated based on an ideal blood parameter curve from a previously performed blood treatment (page 9, lines 16-17 in the Remarks section of the amendment filed 1/25/2006). Examiner maintains the rejection of claims 2, 6, 12, 16, & 21 as taught by Sites in view of Osten, as shown previously, Osten discloses an extracorporeal blood loop permitting real time monitoring of changes in the values of blood parameters (col. 16, lines 44-55). Further, Osten discloses real time monitoring of spectral data and the use of mathematical correlation (ideal curve correlation) in order to monitor hematocrit hemoglobin concentration. Osten discloses using a spectrometer to measure the spectra data of blood when a

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extracorporeal loop is initially formed, and this initial blood curve is compared to further and subsequent blood spectral data measurements within the extracorporeal loop, therefore reading on applicants claimed limitation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-5, 7-11, 13-15, & 17-20 rejected under 35 U.S.C. 102(b) as being anticipated by Sites et al. (USPN '233 B1, hereinafter Sites).

**Claims 1, 3-5, 7-11, 13-15, & 17-20**

Sites discloses a blood treatment device comprising a treating means that performs a predetermined treatment to blood collected from a patient (abstract), a measuring means that measures blood parameters and indicates the status of said blood of said patient, a controlling means that controls treatment conditions based on said blood parameters measured using said measuring means, a storing means that stores an ideal patient-specific blood parameter curve for a specific treatment duration, and a directing means that compares said ideal parameter curve stored in said storing means with blood parameters measured with said measuring means (col. 2, lines 62-64), and that changes the control from said controlling means so that said measured blood parameters approximate to said ideal blood parameter curve (col. 2, line 20-col. 3, line 14,

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col. 6, lines 4-56, col. 7, line 51-col. 8, line 6, col. 8, line 60-col. 9, line 7, col. 9, line 52-col. 10, line 37, col. 11, line 39-col. 13, line 33, & col. 14, line 37-col. 18, line 49).

Sites further discloses wherein the treatment system changes/corrects the treatment parameters based on measured results which are changing over time. It is inherent that over time the measured results of the blood circulated through the treatment system will change over time and also those changes in results are patient specific, whether that change is abrupt or a subtle change over time, the treatment system disclosed by Sites will change the operating parameters of the system (i.e. treatment duration, addition of various drugs to the circulated blood, etc...). Sites discloses comparing the measured parameters to stored parameter baseline values stored in a computer system as disclosed in the cited passages within Sites above.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2, 6, 12, 16, & 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Sites in view of Osten et al. (USPN '133, hereinafter Osten).

### **Claims 2, 6, 12, 16, & 21**

Sites substantially teaches the claimed invention except that it fails to show an approximation function/equation calculated based on an ideal blood parameter (such as hematocrit) curve from a previously performed blood treatment. Osten shows that it is known to

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provide an approximation function/equation calculated based on an ideal blood parameter (such as hematocrit) curve from a previously performed blood treatment (abstract, col. 8, lines 51-59, col. 13, line 30-col. 14, line 67, col. 15, lines 16-39, col. 16, lines 19-25 & lines 38-55, col. 17, line 50-col. 18, line 4) for an blood treatment apparatus. It would have been obvious to someone of ordinary skill in the art to combine the device of Sites with the approximation correlation of Osten for the purposes of providing monitoring the property of interest within a patient nearly simultaneously with changes in that property of interest (Osten, abstract).

### *Conclusion*

**4. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juan D. Valentin II whose telephone number is (571) 272-2433. The examiner can normally be reached on Mon.-Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Juan D Valentin II  
Examiner 2877

JDV

April 16, 2006



**LAYLA G. LAUCHMAN**  
**PRIMARY EXAMINER**